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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT PAPER NUMBER

3736

DATE MAILED: 11/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/865,195

Applicant(s)

HUNTER ET AL.

Examiner

Brian Szmaj

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☒ Claim(s) 80-82 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims pending in the application are 1,3-6,8,9,11-258,262-266,271,273-275,278-281,286,288-291,294,298,300-303,309,311-313,321-323,328,330,331,336,338-341,346-348,353,354 and 358-375.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 3,4,6,13,14,16,17,21-42,202-206,231,232,239-242,247-253,255-258,262-266,271,273-275,278-281,286,288-291,294,298,300-303,309,311-313,321,328,330,331,336,338-341,346-348,353,354,367-372 and 375.

Continuation of Disposition of Claims: Claims rejected are 1,5,8,9,11,12,15,18-20,57,66-79,83,182,201,207,208,220-222,230,358-366,373 and 374.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 9, 2004 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 5, 8, 12, 15, 18-20, 57, 66-77, 182, 201, 207, 208, 220-222, 230, 358-366, 373 and 374 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slater et al in view of Brem et al ('986).

Slater et al disclose radioactive therapeutic seeds and spacers for separating the seeds and further disclose; the radioactive source is selected from I-125, Pd-103, Ir-192, Co-60, Cs-137 and Ru-106; the radioactive source comprises a plurality of seeds; the radioactive source is positioned into tissue of a patient adjacent to a site to be treated by radiation; the radiation prevents cellular proliferation; the cellular proliferation is due to cancer; the radioactive source is administered within a body cavity; the radioactive

source is administered directly into a body tissue; the disease of the prostate is prostate cancer; the spacer is positioned between adjacent seeds, the spacers holding the adjacent seeds apart and holding the plurality of seeds together as part of a continuous thread, and comprising of a bioabsorbable material; and the seeds and spacers are sized to be received in a catheter for insertion into the tissue. See Column 1, lines 15-22 and 54-58; and Column 7, lines 35-54.

Even though Slater et al disclose a bioabsorbable spacer for use with the radioactive seeds, Slater et al fails to disclose a polymer with a cell-cycle inhibitor; the polymer comprises poly(lactic acid); the cell-cycle inhibitor is an alkylating agent; and the cell-cycle inhibitor comprises paclitaxel.

Brem et al disclose controlled local delivery of chemotherapeutic agents for treating solid tumors and further disclose a polymer with a cell-cycle inhibitor; the polymer comprises poly(lactic acid); the cell-cycle inhibitor is an alkylating agent; and the cell-cycle inhibitor comprises paclitaxel. See Column 5, lines 25-49; Column 7, lines 32-49; Column 11, lines 60-67; and Column 12, lines 1-24.

Since both Slater et al and Brem et al disclose means for treating tumors, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system and method of Slater et al to include the use of a biodegradable polymer with a cell-cycle inhibitor, as per the teachings of Brem et al, since it would provide a spacer that has a means of providing localized chemotherapy along with localized radiation from the seed at a tumor site. One of ordinary skill in the art at the time the invention was made would have been able to determine that the

"bioabsorbable spacer" of Slater et al would be composed of a polymer, since Brem et al disclosed such bioabsorbable polymers well before the current priority date of the current Application.

4. Claims 9, 11 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slater et al and Brem et al ('986) as applied to claims 1 and 19 above, and further in view of Mavity et al ('057).

Slater et al and Brem et al, as discussed above, disclose means for providing localized radiation and chemotherapy to a tumor site, but fail to disclose the radiation is released from the polymer; the polymer is a biodegradable polymer; and the use of a cell-cycle inhibitor carried by the outer member on the radioactive seed.

Mavity et al disclose absorbable brachytherapy and chemotherapeutic delivery devices and methods and further disclose the radiation is released from the polymer; the polymer is a biodegradable polymer; and a cell-cycle inhibitor carried by the outer member on the radioactive seed. See Column 12, lines 31-33 and 46-48.

Since Slater et al, Brem et al and Mavity et al disclose means for delivering localized radiation and chemotherapeutic substances to a tumor site, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device and method of Slater et al and Brem et al to include the use of a coating on the radioactive seed for delivering the cell-cycle inhibitor, as per the teachings of Mavity et al, since it would provide a means of delivering radiation and a chemotherapeutic agent to the exact same spot utilizing a single implant rather than have a chemotherapeutic agent adjacent a radioactive seed.

5. Claims 78 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slater et al and Brem et al as applied to claim 57 above, and further in view of Barrows et al.

Slater et al and Brem et al, as discussed above, disclose bioabsorbable articles, but fail to disclose the process of forming the articles, namely the spacer material having a liquid phase and a solid phase.

Barrows et al disclose a bioabsorbable material matrix and further disclose the material of polylactic acid having a liquid phase and a solid phase for forming various articles. See Column 6, lines 1-15 and 45-65; and Column 7, lines 9-29.

Since Slater et al, Brem et al, and Barrows et al disclose means for bioabsorbable articles, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Slater et al and Brem et al to include the disclosure of the bioabsorbable compound having a liquid phase and a solid phase, as per the teachings of Barrows et al, since a liquid phase provides a means of forming various bioabsorbable articles and numerous shapes.

Allowable Subject Matter

6. Claims 80-82 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

7. Applicant's arguments filed June 9, 2004 have been fully considered but they are not persuasive. The Examiner respectfully traverses regarding the Applicant's argument that the combination of Slater et al and Brem et al fail to teach or suggest the current invention. Even though the disclosure of a bioabsorbable spacer in Slater et al is broad, and does not explicitly disclose at least one specific bioabsorbable polymer, one of ordinary skill in the art would have been able to recognize the disclosure of a bioabsorbable spacer includes spacers that are made out of bioabsorbable polymers such as those disclosed in Brem et al. Brem et al disclosed such bioabsorbable polymers that can be used in conjunction with radiation therapy in an Application filed on August 2, 1994, well before the invention of Slater et al which was filed on August 12, 1998. Therefore, the disclosure of a bioabsorbable spacer in Slater et al would clearly anticipate the use of at least one of the disclosed polymers in Brem et al, such that one of ordinary skill in the art would be able to produce the current device and treat cancer using the combination of brachytherapy seeds and chemotherapeutic spacers. Based on the disclosure of Brem et al, there is no suggestion that small spacers could not be made from the disclosed polymers. Specifically, Brem et al discloses the creation of a 2.5 mm implant utilizing a mold (See Column 14, lines 54-58). Since the disclosed polymers of Brem et al can be molded into at least one shape for an implant, it would have been reasonable that one of ordinary skill in the art would be able to create a brachytherapy seed spacer utilizing the same polymers with the disclosed chemotherapeutic drugs dispersed within the polymeric matrix with a degree of success. Therefore, the combination of Slater et al and Brem et al clearly disclose the claimed

device and method of treating cancer using the combination of brachytherapy seeds and chemotherapeutic spacers.

8. In response to applicant's argument that it would have not been obvious to one of ordinary skill in the art to combine the references of Slater et al and Brem et al to achieve a radioactive seed and therapeutic bioabsorbable spacer, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

9. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the invention of Brem et al was filed on August 2, 1994, disclosing the use of biodegradable polymers with chemotherapeutic drugs incorporated within the matrix to produce bioabsorbable chemotherapeutic products that are usable in conjunction with radiation therapy (See Column 11, lines 60-67; and Column 12, lines 1-24), and the invention of Slater et al, filed on August 12, 1998, discloses the use of bioabsorbable spacers coupling

radioactive seeds. Brem et al provides the motivation for the combination of Brem et al and Slater et al to disclose the current invention, due to the use of implants composed of a bioabsorbable matrix with chemotherapeutic agents in the matrix that are usable in conjunction with radiation therapy to treat cancer, while Slater et al explicitly disclose the type of radiation therapy being brachytherapy seeds.

10. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

11. This is an RCE of applicant's earlier Application No. 09/865,195. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmalec whose telephone number is (703) 308-3737. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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